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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 10/823,043 | 04/12/2004 | Barrie Tan | BT-001 | 4102 |
| 38051 | 7590 | 02/27/2006 | EXAMINER | |
| KIRK HAHN 14431 HOLT AVE SANTA ANA, CA 92705 | | | MCCORMICK EWOLDT, SUSAN BETH | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1655 | |
| DATE MAILED: 02/27/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/823,043

Applicant(s)

TAN ET AL.

Examiner

S. B. McCormick-Ewoldt

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-10 and 25-36 is/are pending in the application.
- 4a) Of the above claim(s) 25-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment of December 12, 2005 is hereby acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant elected Group I and species, palm extract, in the reply filed July 21, 2005.

Newly submitted claim 25 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant has added claims 26-36 as being directed to non-elected Groups II-VII, being process claims. Applicant is advised that at such a time as elected product claim(s) are indicated as being allowable, rejoinder of claims drawn to methods of using such may be requested under 35 U.S.C. § 103(b) pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86). Such a rejoinder is *not* tantamount to a withdrawal of the restriction requirement. However, as Applicant has chosen to elect a product and not a method; accordingly, rejoinder in view of the *Ochai* decision is not applicable to this case.

Claims Pending

Claims 1-5, 7-10 and 25-36 are pending. Applicant has cancelled claims 6 and 11-24.

Claim Rejections - 35 USC § 102

Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Tan (US 6,350,453) as stated previously in the prior Office action. Applicant's arguments filed December 12, 2005 have been fully considered but they are not persuasive.

Tan (US 6,350,453) teaches that *Bixa orellana* (i.e. annatto) contains tocotrienols and are known to have beneficial effects against hypocholesterolemia, reduce lipoprotein plasma levels

Art Unit: 1655

and be useful in the treatment of cardiovascular disease (column 1, lines 10-47). Tan *et al.* also disclose a method to separate tocopherols and tocotrienols so essentially no tocopherols are present (column 2, lines 4-6, 18-20, 45-49). Thus Tan anticipates the claimed invention.

Applicant argues that Tan does not disclose a “composition of annatto extract and an ingredient of tocol containing material or non-tocol containing material, wherein greater than 60% of the tocols are tocotrienols.” This is not found persuasive because Tan discloses the concentration of distilled tocotrienol in a range between 20 weight percent and about 90 weight percent (column 5, lines 40-42).

Claim Rejections - 35 USC § 103

Claims 1-5 and 7-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tan (US 6,350,453), in view of Wright *et al.* (US 5,217,992) and in view of Levy *et al.* (US 2003/0104090) as stated previously in the prior Office action. Applicant's arguments filed December 12, 2005 have been fully considered but they are not persuasive.

Tan (US 6,350,453) disclose that *Bixa orellana* (i.e. annatto) contains tocotrienols and are known to have beneficial effects against hypocholesterolemia, reduce lipoprotein plasma levels and be useful in the treatment of cardiovascular disease (column 1, lines 10-47). Tan *et al.* also disclose a method to separate tocopherols and tocotrienols so essentially no tocopherols are present (column 2, lines 4-6, 18-20, 45-49). Tan does not disclose specifically using alpha-T1, delta-T3 or gamma-T3.

Wright *et al.* (US 5,217,992) disclose delta and gamma tocotrienols in palm oil act as inhibitors of lowering serum total cholesterol and LDL-cholesterol in humans (column 4, lines 23-33).

Levy *et al.* (US 2003/0104090) discloses that annatto extracts (i.e. *Bixa orellana*) contains vitamin E tocotrienol ([0002]). Levy *et al.* disclose that therapeutic health benefits also include improving symptoms of diabetes, inhibiting atherosclerosis and/heart disease, lowering LDL cholesterol and protecting neuron cells from being killed due to stroke, inflammation or neurodegenerative disease ([0016] and [0034]).

Art Unit: 1655

Applicant argues that independent claim 1 and dependent claim 2 contain the limitation of “greater than 60% of the tocols are tocotrienols.” This is not found persuasive because Tan discloses the concentration of distilled tocotrienol in a range between 20 weight percent and about 90 weight percent (column 5, lines 40-42). In addition, Applicant argues that claim 3 have the further limitation of “less than 40% of the tocols are tocopherols.” This is not found persuasive because one of ordinary skilled in the art would optimize the amount of tocotrienols and tocopherols in a composition and would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and it would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in order to best achieve the desired results.

Therefore the rejection is deemed proper and is maintained.

Summary

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

Art Unit: 1655

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Terry McKelvey, can be reached on (571) 272-0775. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

PATRICIA LEITH
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Patricia Leith", written over the printed name and title.